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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/198,798 11/24/98 LICHTEN

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EXAMINER

BADIO, B

ART UNIT

PAPER NUMBER

1616

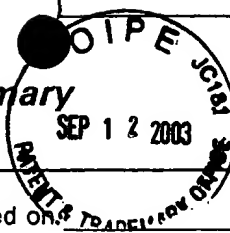
DATE MAILED: 02/21/01

HM12/0221
GIFFORD KRASSS GROH SPRINKLE PATMORE
ANDERSON & CITKOWSKI P.C.
280 N OLD WOODWARD AVENUE
SUITE 400
BIRMINGHAM MI 48009-5394

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/198,798

At

Lichten

Examiner
Barbara BadioGroup Art Unit
1616☐ Responsive to communication(s) filed on _____.☒ This action is **FINAL**.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-14 and 30-50 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.☒ Claim(s) 1-14 and 30-50 is/are rejected.☐ Claim(s) _____ is/are objected to.☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on _____ is/are objected to by the Examiner.☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number) _____.☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. **The rejections of claims 1-6, 8-13, 30-35, 37-42, 44 and 46-50 under 35 USC 112, first paragraph are maintained.**

Applicant argues that the examiner has not shown why reference to analogs, derivatives etc. would require undue experimentation because the examiner has not examined the *In re Wands* factors. Applicant's argument was considered but not persuasive for the following reason.

The rejections are "scope of enablement" and "written description" and not "lack of enablement" which would require an examination of the Wands factors. The instant claims are enabled for testosterone and compounds recited by the present specification. However, the present specification lacks description of the various terms that are the basis of the rejections and, thus, does not provide enablement for compounds not recited by the present specification.

For this reason and those given in Paper No. 9, the rejections of claims 1-6, 8-13, 30-35, 37-42, 44 and 46-50 under 35 USC 112, first paragraph are maintained.

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3. **The rejection of claims 1-14 and 30-50 under 35 USC 112, first paragraph (i.e. item #5 of the previous Office Action) is withdrawn.**

4. **The rejection of claims 1-14, and 30-50 under 35 USC 112, second paragraph is maintained.**

Applicant argues that the meaning of the terms, for example prodrugs, used by the instant claims are clear and definite. In addition, applicant implies that claims 7, 14, 36, 43 and 45 recites "comprises" and, thus, the claims are not limited to dihydrotestosterone. Applicant's arguments were considered but not persuasive for the following reasons.

In regards to claims 7, 14, 36, 43 and 45, the issue was not the make up of the preparation administered but whether the claims included other derivatives as recited by claim 1. Based on applicant's argument as to the meaning of "comprises", the examiner assumes the claims are intended to include all derivatives, analogs etc. as long as dihydrotestosterone is one of the compound included in said group.

In response to applicant's argument that the terms "analogs", "derivatives" and/or "prodrugs" are known in the art or adequately described by the present specification, the examiner notes that the issue is not whether the ordinary artisan knows the meaning of the terms but whether he would be able to ascertain the metes and bound of the claimed invention. In other words, whether the ordinary artisan would

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be able to determine what is encompassed by the instant claims. The examiner maintains the position that the use of "analogs", "derivatives" and "prodrugs" in the instant claims creates confusion because the ordinary artisan would be unable to determine the metes and bound of the claimed invention.

For these reasons and those given in Paper No. 9 , the rejection of claims 1-14, and 30-50 under 35 USC 112, second paragraph is maintained.

5. The rejection of claim 2 under 35 USC 112, second paragraph, lack of antecedent basis is withdrawn.

6. The rejection of claims 2, 4, 5, 9, 11, 12, 31, 33, 34, 38, 40, 41, 46, 48 and 49 under 35 USC 112, second paragraph as being indefinite for use of the term "includes" is maintained.

Applicant argues that the term is similar to "comprising" and is intended to cover the structural elements recited plus additional elements. Applicant argument was considered but not persuasive for the following reason.

As used in the instant claims, the term "includes" is indefinite because it is unclear whether the limitation following "includes" is a part of the claimed invention. The phrase "the step of administering includes the testosterone" would imply that said administration of testosterone is not included in the parent claim or is not part of

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the present invention. If applicant wants to include additional elements, the phrase "the step of administering includes the testosterone" does not accomplish that which applicant intends. It implies that applicant's claimed invention excluded the administering of testosterone which is now included as a limitation of the instant claims.

For this reason and those given in Paper No. 9, the rejection of claims 2, 4, 5, 9, 11, 12, 31, 33, 34, 38, 40, 41, 46, 48 and 49 under 35 USC 112, second paragraph as being indefinite for use of the term "includes" is maintained.

Claim Rejections - 35 USC § 102

7. The rejection of claims 1, 2, 8, 9, 30, 31, 37, 38, 44 and 46 under 35 USC 102(b) over Coleman et al. is maintained.

Applicant argues that the claims as amended include the limitation of identifying a human subject and Coleman does not suggest or teach that DHEA can be used in human as an antihyperglycemic or antidiabetic agent. Applicant argument was not persuasive for the following reasons.

A prior art may anticipate when complete anticipation requires only that one skilled in the art merely exercise that skill to complete the work, i.e., could practice the patented invention without having to depend on other prior art or his inventive skills. *Studiengesellschaft Kohle mbH v. Dart Industries, Inc.* (CAFC 1984); *E.I. Du Pont de Nemours & Co. V. Polaroid Graphics Imaging, Inc.* (DCDel 1989) 706 Fsuppl. 1136, 10

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PQ2d,1579. The ordinary artisan in the art at the time of the invention would know that tests done in mice can be extrapolated to human and, thus, would know that the antihyperglycemic or antidiabetic effect shown by Coleman in mice would be applicable to human.

For these reasons and those given in Paper No. 9, the rejection of claims 1, 2, 8, 9, 30, 31, 37, 38, 44 and 46 under 35 USC 102(b) over Coleman et al. is maintained.

8. The rejection of claims 1, 2, 8, 9, 30, 31, 37, 38, 44 and 46 under 35 USC 102(b) over Moller et al. and Mauriello et al. is maintained.

Applicant argues that Mauriello (1) does not teach selecting patients based on a predetermined testosterone ratio; (2) is oriented to a different problem and (3) does not suggest that it can be combined with other references to obtain the claimed invention. Applicant also argues that Moller (1) involves the treatment of cardiovascular disease and not insulin resistance and (2) does not teach selecting patients with insulin resistance and selecting them based on testosterone ratios. Applicant's arguments were considered but not persuasive for the following reasons.

As stated above, a prior art may anticipate when complete anticipation requires only that one skilled in the art merely exercise that skill to complete the work, i.e., could practice the patented invention without having to depend on other prior art or his inventive skills. *Studiengesellschaft Kohle mbH v. Dart Industries, Inc.* (CAFC 1984);

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E.I. Du Pont de Nemours & Co. V. Polaroid Graphics Imaging, Inc. (DCDel 1989) 706 Fsuppl. 1136, 10 PQ2d 1579. The determination of the presence of insulin resistance in a patient with diabetes is not novel since insulin resistance diabetes is well known in the art. The recitation in the preamble of the claimed invention of selecting the patient based on a predetermined testosterone ratio test, i.e. the relationship between sex hormone-binding globulin (SHBG) and testosterone, does not change the claimed invention of controlling serum-glucose levels by administering testosterone which is the essence of the instant invention. The relationship between SHBG and testosterone is noted in the prior art (see pages 29-48 of the present specification). However, whatever method is used to determine whether one is insulin resistance does not change the fact that the prior art teaches the hypoglycemic effect of testosterone and, thus, its use in treatment of diabetes.

The fact that the references deal also with the treatment of other diseases is not relevant. The issue is whether the prior art teach the hypoglycemic or antidiabetic effect of testosterone. It is the examiner's position that the cited prior art anticipates the use of testosterone in the treatment of diabetic patients.

As for the determination of the amount of testosterone needed to achieve the effect taught by the prior art, the examiner maintains that it requires only routine experimentation and is within the level of skill of the ordinary artisan. Applicant only has to look to the medical art to determine the level of skill of the ordinary artisan in

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determination of the effective amount of any agent. In addition, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

For these reasons and those given in Paper No. 9, the rejection of claims 1, 2, 8, 9, 30, 31, 37, 38, 44 and 46 under 35 USC 102(b) over Moller et al. and Mauriello et al. is maintained.

Claim Rejections - 35 USC § 103

9. **The rejection of claims 1-14 and 30-50 under Coleman et al., Moller et al. or Mauriello et al. is maintained.**

Applicant's arguments and the examiner's response are similar to those given in #s 7 and 8 above. In addition, applicant argues that the determination of the effective amount is not suggested by the prior art and that the cited prior art do not discuss or disclose hemoglobin A1C or Syndrome X in the same manner as the claimed invention. Applicant's argument was considered but not persuasive for the following reasons.

As stated in the present specification, a lowering of insulin resistance is associated with a decrease in hemoglobin A1C (see page 15 of the present invention) and it is known in the art that insulin resistance, glucose intolerance, etc. are factors in Syndrome X. The prior art teaches testosterone lowers insulin resistance (i.e.,

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increases sensitivity to insulin) and, thus, it would follow that there would be a decrease in hemoglobin A1C in patients given testosterone. One can not separate the various properties of a compound. It also follows that a compound that lowers insulin resistance and is antihyperglycemic would be useful in treating Syndrome X. As is known in the art, glucose intolerance, insulin resistance, increased LDL and decreased HDL is associated with both Syndrome X and non-insulin dependent diabetes (see for example Reaven, 1988, page 1605, Abstract and Table 1).

For these reasons and those given in Paper No. 9, the rejection of claims 1-14 and 30-50 under Coleman et al., Moller et al. or Mauriello et al. is maintained.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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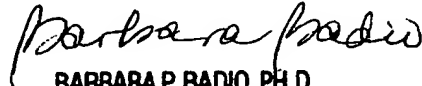
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry Contacts

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara Badio whose telephone number is (703) 308-4595. The examiner can normally be reached between 7:30 am and 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.


BARBARA P. BADIO, PH.D
PRIMARY EXAMINER

February 16, 2001